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To: Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration

Subject: Docket No. FDA–2021–N–0555, RIN 0910-AI21, Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

Dear Commissioner Woodcock,

I am pleased at the opportunity to comment on the draft rule entitled "Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids."

I am an NIH-funded clinician-scientist at Columbia University in New York. I have treated thousands of individuals with age-related hearing loss and run a laboratory investigating the brain effects of untreated age-related hearing loss. One of my areas of focus is improving the accessibility of life-improving hearing technology, which includes over-the-counter (OTC) hearing aids. I am excited to soon see this technology help millions of individuals with hearing loss in an effective and more affordable way than currently possible. To enable this, please consider the following comments:

I strongly support the current proposed maximum output of 120 dB SPL with volume control (115 dB SPL without volume control). **I do not agree with the proposal of a 25 dB gain limitation**. The 25 dB gain limit would reduce the effectiveness of OTC hearing aids and thus limit their widespread adoption among those who could benefit. The currently proposed 120 dB SPL max output is necessary to provide OTC devices with a sufficient dynamic range. Without this, the original sound will be distorted such that clarity and effectiveness will suffer. The proposed 120 dB SPL max output limit is sufficiently strict to give users time to remove OTC aids before output levels become dangerous.

I agree with the current inclusion of minimum technologic specifications such as permissible internal noise levels, response range, latency, and so forth. This will ensure that OTC hearing aids meet a minimum standard for safety and effectiveness.

I strongly recommend that the FDA clarify that OTC hearing aids refer specifically to *self-fitting* devices by definition, which would then require a 510(k) review. Self-fitting is fundamental to functionally effective OTC devices. Without this important clarification, it is possible that in the immediate future, companies will try to market OTC hearing aids that are *not*

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self-fitting as a strategy to avoid 510(k) review and bring their products to market quicker and more easily. However, such non-self-fitting products would be far less effective and would tarnish the overall reputation of the OTC hearing aid category. This could lead to widespread distrust and lower use of the OTC device category, exactly the opposite of the desired result. At the same time, however, it is important to facilitate innovation and bring quality products to market. In order to do this, I recommend clear guidelines on what is needed for the 510(k) review. Furthermore, in 1-2 years after the regulations become active at which time there will be more experience, the FDA should consider an exemption for OTC self-fitting hearing aids from the 510(k) pathways.

Thank you for considering my comments and for your work in improving access to technology that will improve hearing healthcare.

Sincerely,

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